DEC 19 2013

510(k) Summary

510(k) Number: K130579

1. Submitter Information

Submitter Name:	Physician Software Systems, LLC 3333 Warrenville Road, Suite 200 Lisle, Illinois 60532 Phone: 331-213-9000 Fax: 331-213-9009
Contact Person:	Lewis A. Mitchell Chief Executive Officer
Date Prepared:	December 18, 2013

2. Name of Device

Trade Name	PhySoft AMS™
Classification Name	Hemodialysis System and Accessories
Classification Panel	76 Gastroenterology/Urology
Classification Regulations	876.5820
Product Code	MQS
Device Classification	Class II

3. Predicate Device Information

Trade Name	Crit Line Anemia Management (CLAM)
510(k)	K093834
Classification Name	Hemodialysis System and Accessories
Classification Regulations	876.5820, 862.2100

Product Code	MQS, JQP
Device Classification	Class II

4. Intended Use

PhySoft AMS™ is a web application used to obtain, track and trend patient data pertaining to the management of anemia, and to provide a schedule of erythropoiesis-stimulating agent (ESA) dosage recommendations to help achieve and maintain target hemoglobin levels in dialysis patients. PhySoft AMS™ is intended to help physicians, nurses, clinicians and anemia managers manage anemia in adult stage 5 chronic kidney disease (CKD) patients.

The PhySoft AMS™ is not a substitute for, but rather intended to assist, clinical judgment. The ESA dosing regimen options calculated by this device are intended to be used by qualified and trained medical personnel to inform the optimization of the dosage of ESAs in accordance with their approved labeling in conjunction with clinical history, symptoms, and other diagnostic measurements, as well as the medical professional's clinical judgment. No medical decision should be based solely on the patient Hgb response to dosing regimen options calculated by this device.

5. Device Description

PhySoft AMS™ is a software application used to obtain, track and trend patient data pertaining to the management of anemia, and to provide a schedule of ESA dosage recommendations to help achieve and maintain target Hgb levels in dialysis patients. PhySoft AMS™ is intended to help physicians, nurses, clinicians and anemia managers manage anemia in adult stage 5 CKD patients.

PhySoft AMS™ is intended for use by medical personnel such as clinicians, nurses, and physicians in dialysis clinics or other settings where anemia management for hemodialysis patients is conducted.

Healthcare professionals access PhySoft AMS™ using a web browser communicating with the PhySoft AMS™ web application server. Patient information is obtained by PhySoft AMS™ from healthcare provider information systems. No components of PhySoft AMS™ are required to be installed at end user or healthcare provider locations.

PhySoft AMS™ assesses if there is adequate data to model an individual patient's Hgb response to ESAs. The results of this assessment are reviewed by the physician who, after considering any additional relevant information about the patient's condition,

decides if they want to apply the PhySoft AMS™ ESA dose-Hgb response modeling capability to the particular patient's data. If adequate data are available, PhySoft AMS™ enables a physician to model a patient and select from dosing schedule options to achieve target Hgb levels or, at the physician's discretion, override the presented dosing schedule options.

6. Technological Characteristics

Both PhySoft AMS™ and CLAM are software application to record, track, and trend patient data, and provide ESA dosage recommendations in accordance with the ESA approved labeling. The table below compares the similarities of PhySoft AMS™ to the predicate device (CLAM) with respect to technological characteristics.

Similarities to CLAM (Predicate Device)		
Item	**PhySoft AMS™**	**Predicate Device (CLAM)**
Indications for Use	Management of anemia in dialysis patients under ESA treatment	Same
Principle of Operation	Track and trend Hgb and ESA dosages which can be used to determine future ESA dosages	Same
Technology	Application used to trend patient data collected during each dialysis treatment	Same
Patient Demographics	Adult stage 5 chronic kidney disease patients	Same
Intended User	Physician/Clinicians/Nurses	Same
Data Storage	Data is stored electronically	Same
Data Management	Generates reports and graphs to assist anemia management	Same
Safeguards/Alerts	System flags patients who exceed limits	Same

Differences between PhySoft AMS™ and the predicate device (CLAM) are summarized in the table below.

Differences with CLAM (Predicate Device)		
Item	**PhySoft AMS™**	**Predicate Device (CLAM)**
Technology/Algorithm	Uses individualized dose-response model to compute patient dose-response. Accounts for the effect of multiple prior ESA dosages Estimates ongoing dosing schedules to achieve target Hgb levels	Uses a fixed phenomenological dose-response model for all patients. Accounts for the effect of the last ESA dosage Provides a single ESA dosing recommendation to achieve a change in Hgb trend
Data Entry	Patient data is transferred electronically from existing healthcare provider information systems.	Patient data is obtained from a combination of healthcare provider manual data entry and directly from a Hgb measurement device.
Data Storage	Data is stored electronically on local or remote database server	Data is stored electronically on computer media or networked server
Data Network Access	Data is accessed over secure Internet connections	Data is accessed on local computer or network
Safeguards/Alerts	System flags patients who do not respond as predicted and may have undetected health issues that do not fit the most probable model. Evaluates patient readiness for application of algorithm to model ESA dose-Hgb response (sufficient history of Hgb and ESA dosing).	System flags patients exceeding target limits but does not flag patients who do not respond as predicted over time. Does not evaluate patient readiness.

7. Performance Data

The software validation, bench testing, and a clinical evaluation were conducted for PhySoft AMS™. The Performance data demonstrated the safety and effectiveness of PhySoft AMS™ in anemia management for hemodialysis patients.

8. Conclusion

PhySoft AMS™ and CLAM are substantially equivalent with respect to intended use, technological characteristics, and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 19, 2013

Physician Software System, LLC
Lewis A. Mitchell
Chief Executive Officer
3333 Warrenville Road, Suite 200
Lisle, IL 60532

Re: K130579
Trade/Device Name: PhySoft AMS™
Regulation Number: 21 CFR 876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: Class II
Product Code: MQS
Dated: November 8, 2013
Received: November 12, 2013

Dear Lewis A. Mitchell,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Glen FDA Bell -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K130579

Device Name: PhySoft AMS™

Indications for Use:

PhySoft AMS™ is a web application used to obtain, track and trend patient data pertaining to the management of anemia, and to provide a schedule of erythropoiesis-stimulating agent (ESA) dosage recommendations to help achieve and maintain target hemoglobin levels in dialysis patients. PhySoft AMS™ is intended to help physicians, nurses, clinicians and anemia managers manage anemia in adult stage 5 chronic kidney disease (CKD) patients.

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Prescription Use YES (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use NO (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Glenn B. Bell -S